



CONGRESSIONAL BUDGET OFFICE

COST ESTIMATE

June 16, 1999

S. 6

Patients' Bill of Rights Act of 1999

As modified by the sponsors

SUMMARY

The Patients' Bill of Rights Act of 1999 would impose new requirements on the structure and operation of group health plans and health insurance issuers and would provide members of health plans and insured individuals with new rights to obtain certain health care services. It would require both internal and external review processes for members to appeal decisions by health plans and insurers. It would also amend the Employee Retirement Income Security Act (ERISA) to allow individuals to sue health plans and insurers for personal injury or wrongful death under state tort laws. These provisions would have a significant effect on the costs of private insurance as well as the federal budget. Because of the extent and complexity of the changes to the health insurance system that could result from such provisions, estimates of their effects are subject to more than the usual amount of uncertainty.

The bill would affect the federal budget in three ways. First, by increasing premiums for employer-sponsored health benefits, it would substitute nontaxable employer-paid premiums for taxable wages and would therefore decrease federal income and payroll tax revenues. The Congressional Budget Office (CBO) estimates that the proposal would reduce federal tax revenues by \$390 million in 2000 and by \$7.0 billion over the 2000-2004 period. Second, the bill would impose additional costs on the Federal Employees' Health Benefits Program, most of whose plans are classed as health insurance issuers. CBO estimates that these costs would amount to \$240 million over the 2000-2004 period, of which \$95 million would be mandatory. Third, it would require additional spending for administration and regulatory activities, subject to appropriation of the necessary amounts. These discretionary costs would total an estimated \$315 million over the next five years. CBO recognizes that this bill could affect practice styles in fee-for-service settings, potentially raising fee-for-service expenditures under Medicare. CBO has not estimated the magnitude of such an effect.

The bill's requirements on group health plans offered by state, local, and tribal governments would be optional under the Public Health Service Act (PHSA). Consequently, those requirements would not be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

The bill would establish several private-sector mandates as defined by UMRA. Provisions imposing new functions and operating practices on private insurers and health plans would create private-sector mandates. Provisions that would indirectly raise plan costs, such as those giving plan members the right to sue plans for personal injury, would not be considered private-sector mandates. The estimated costs of the private-sector mandates would greatly exceed the annual threshold established in UMRA (\$100 million in 1996, adjusted for inflation) in each of the years after enactment. CBO estimates that the cost of private-sector mandates would total about \$41 billion over the 2000-2004 period.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of the bill is shown in Table 1. The costs of this legislation fall within budget function 500 (health) and other functions.

BASIS OF ESTIMATE

The bill would significantly change the relationships between employers, health plans, health insurers, providers, and patients. These changes would be complex and would be imposed on a rapidly evolving health care system. In some areas, limited data on which to base a cost estimate are available. CBO has consulted with a variety of experts, including representatives of managed care plans, health insurers, providers, and private industry; state regulators; practicing and academic health and ERISA lawyers; and health policy researchers. Although this cost estimate is subject to more than the usual amount of uncertainty, it represents CBO's best judgment about the likely effects of the bill. The ultimate costs could be substantially larger or smaller.

TABLE 1. ESTIMATED BUDGETARY EFFECT OF THE PATIENTS' BILL OF RIGHTS ACT

	By Fiscal Year, in Millions of Dollars									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
REVENUES										
Income and HI Payroll Taxes	-270	-680	-1,070	-1,320	-1,530	-1,660	-1,750	-1,850	-1,950	-2,060
Social Security Payroll Taxes	<u>-120</u>	<u>-300</u>	<u>-470</u>	<u>-580</u>	<u>-680</u>	<u>-730</u>	<u>-770</u>	<u>-820</u>	<u>-860</u>	<u>-910</u>
Total	-390	-980	-1,540	-1,900	-2,210	-2,390	-2,520	-2,670	-2,810	-2,970
DIRECT SPENDING										
FEHBP—Annuitants	5	10	20	25	35	40	45	45	50	55
AUTHORIZATIONS OF APPROPRIATIONS										
FEHBP—Active Workers	5	15	30	40	55	60	65	70	75	75
Federal Administrative Costs	<u>25</u>	<u>70</u>	<u>70</u>	<u>75</u>	<u>75</u>	<u>75</u>	<u>80</u>	<u>80</u>	<u>80</u>	<u>85</u>
Total	30	85	100	115	130	135	145	150	155	160

SOURCES: Congressional Budget Office and Joint Committee on Taxation.

NOTES: HI = Hospital Insurance
FEHBP = Federal Employees Health Benefits Program

CBO estimated the impact of each provision on health plan premiums in the 10 years following enactment (which is assumed to occur by October 1, 1999). This cost impact is expressed as the expected ultimate percentage change in average health insurance premiums—that is, the change when all of the bill's provisions are fully phased in. Most of the provisions would reach their full effect within the first 3 years after enactment. CBO estimates that premiums for employer-sponsored health plans would rise by an average of 4.8 percent in the absence of any compensating changes on the part of employers. Table 2 shows the estimated effect of each provision on premiums, before employers modify their behavior to offset some of the increase. The effects are expressed as a percentage of total premiums for all nonfederal employer-sponsored plans, including plans that would face no increase in costs.¹

1. Most of the provisions of the bill were extended to the Federal Employees Health Benefits Program under a Presidential memorandum of February 20, 1998. On April 9, 1999, the President announced that two additional provisions would be included. This estimate includes the costs of the provisions of the bill that cannot be implemented administratively.

Employers could respond to premium increases in a variety of ways to reduce their impact. They could drop health insurance entirely, reduce the generosity of the benefit package, increase cost-sharing by beneficiaries, or increase the employees's share of the premium.

TABLE 2. ESTIMATED ULTIMATE EFFECT OF THE PATIENTS' BILL OF RIGHTS ACT ON PREMIUMS FOR EMPLOYER-SPONSORED HEALTH INSURANCE (In percent)

Provision	Increase in Premiums
Section 101—Access to Emergency Care	0.4
Section 102—Offering of Choice of Coverage Options	0.2
Section 103—Choice of Providers	a
Section 104(a)—Obstetrical and Gynecological Care	0.1
Section 104(b)—Specialty Care	a
Section 105—Continuity of Care	0.2
Section 106—Coverage for Clinical Trials	0.5
Section 107—Access to Needed Prescription Drugs	b
Section 108—Adequacy of Provider Network	0.2
Section 109—Nondiscrimination in Delivery of Services	0.1
Section 111—Internal Quality Assurance Program	0.2
Section 112—Collection of Standardized Data	0.2
Section 113—Process for Selection of Providers	b
Section 114—Drug Utilization Program	b
Section 115—Standards for Utilization Review Activities	b
Section 116—Health Care Quality Advisory Board	0
Section 121—Patient Information	b
Section 122—Protection of Patient Confidentiality	b
Section 123—Health Insurance Ombudsmen	0
Section 131—Establishment of Grievance Process	0.3
Section 132—Internal Appeals of Adverse Determinations	c
Section 133—External Appeals of Adverse Determinations	c
Section 141—Prohibition of Interference	b
Section 142—Prohibition of Improper Incentive Arrangements	b
Section 143—Participation of Health Care Professionals	0.2
Section 144—Protection for Patient Advocacy	d
Section 151—Promoting Good Medical Practice	0.8
Section 152—Standards for Breast Cancer Treatment	b
Section 302—ERISA Preemption	<u>1.4</u>
Total	4.8

a. Included in estimate of section 108.

b. Less than 0.05 percent.

c. Included in estimate of section 131.

d. Included in estimate of section 143.

CBO assumed that employers would deflect about 60 percent of the increase in premiums through these strategies. The remaining increase in premiums would be passed on to workers in the form of lower wages. These lower wages would reduce federal receipts from income and payroll taxes.

The bill would somewhat reduce the ability of managed care organizations to limit the use of health care services. The loosening of styles of practice by providers in managed care plans could spill over to other settings, raising costs to some degree in fee-for-service plans and potentially raising fee-for-service expenditures under Medicare. That conclusion is based on recent studies that found lower fee-for-service expenditures under Medicare in areas of the country with greater market penetration by HMOs. Those results suggest that providers who participate in managed care plans change their practice styles for all of their patients, not just for those enrolled in HMOs. Decreasing the restrictiveness of managed care plans could, as a result, lead to higher costs in fee-for-service plans as well. CBO has not estimated the magnitude of such an effect for either Medicare or private insurance.

Title I of the bill, comprising seven subtitles, would establish standards to protect consumers and providers in managed care plans and other health insurance plans. Title II would apply the standards to group health plans and issuers of individual health insurance coverage as defined in title XXVII of the Public Health Service Act. Title III would apply the standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act. Title IV would apply the standards to group health plans under the Internal Revenue Code. In this estimate, the costs of the patient-protection standards are assigned to the corresponding sections of title I.

In addition, title III would amend ERISA to allow enrollees in employer-sponsored health insurance plans to sue their plans under state law for damages resulting from personal injury or wrongful death. It would also require the Secretary of Labor to investigate complaints of discrimination or retaliation against health care professionals. The incremental costs of these provisions are shown separately.

Access to Care

Subtitle A would impose requirements on the structure of health plans and the access to services and providers they offer their members. These requirements would affect access to emergency and specialty care, coverage of clinical trials, and adequacy of provider networks.

Section 101—Access to Emergency Care. This section would require plans to pay for emergency care received without prior authorization in any licensed hospital emergency department when the condition is serious enough to meet the “prudent layperson” standard (as applicable to Medicare+Choice plans). Moreover, the plan could charge the patient no more than if the emergency department were in the plan’s network. CBO assumes, therefore, that the plan would be responsible for paying the non-participating provider’s full charge for emergency services rendered. Finally, the plan would be required to pay for post-stabilization care rendered at the nonparticipating institution consistent with regulations governing Medicare and Medicaid.

Many states have laws in place that require that health plans pay for emergency services; those laws vary widely in their definitions of emergencies and requirements for out-of-network coverage. CBO estimates that about 20 percent of the U.S. population lives in states whose laws fully meet the standard of this section and another 60 percent of the population resides in states with laws that partially conform. CBO assumed that roughly half of current denials of payment for emergency room visits would meet the prudent layperson standard and that the costs to health plans of treating patients in nonparticipating emergency departments would be 50 percent higher than they would be in participating hospitals. Once the prudent layperson standard became widely understood, members of plans would increase emergency visits and probably their use of nonparticipating hospital emergency departments. The return to fee-for-service insurance payment to nonparticipating providers would encourage hospitals to raise their charges for visits to emergency departments. CBO estimates that the new prudent layperson standard, the removal of restrictions on nonparticipating providers’ payment rates, and the inducement of additional visits to emergency rooms would increase the average premium by 0.4 percent across all private employer-sponsored health plans.

Section 102—Offering of Choice of Coverage Options. This section would require health plan sponsors to offer point-of-service (POS) plans whenever their existing offerings of plans did not include a plan that pays for care received from non-network providers. CBO estimates that about 23 percent of employees currently work in organizations offering employee health plans that limit choice of provider and do not offer an alternative plan without such limits. The provision would increase the administrative cost of processing out-of-plan claims and increase the use of services by those who selected the POS option. Because the provision would not impose any requirements on the financial terms of the POS option, employers could offset some of its costs by increasing the cost-sharing requirements for beneficiaries. Based on out-of-plan use in existing preferred provider organization (PPO) and POS plans, CBO estimated that 10 percent of employees in firms newly offering the POS option would select it and that the net costs (benefit payments and administrative expenses)

for those individuals would increase by 11 percent. The net effect averaged across all employer-sponsored health plans would be an increase of 0.2 percent in premiums.

Section 103—Choice of Providers. This section would require health plans to allow enrollees to choose among the participating health care providers who are available to accept patients, but it would allow health plans to restrict choice among specialists if the plan clearly informed participants of these limitations. Alone, this section would have negligible effects on health care costs because it would give plans the right to close physician practices to new patients and would also allow plans to write rules into their description of benefits that detailed limitations on access to specialists. However, this provision would be appealable under sections 132 and 133 and could interact with section 108 (requiring an adequate provider network) as it was considered by appeals bodies. For example, if only one physician in a specific subspecialty was available to see patients at the time of referral, patients might argue on the basis of both this section and section 108 that the plan was not providing a sufficient choice of providers. Because of the interaction of this section with section 108, CBO includes the cost of this section in its estimate of section 108.

Section 104(a)—Obstetrical and Gynecological Care. This subsection would grant women specific rights to designate a participating obstetrical and gynecological specialist as their primary care provider and to receive covered preventive women's health and pregnancy services from a participating obstetrical and gynecological specialist.

This provision would require an immediate change in the design and operation of some plans, but it would not affect all types of plans. Fee-for-service and PPO plans do not require referrals to specialists. In addition, fully-insured ERISA plans and self-purchased insurance products are subject to state mandates on access to obstetrical and gynecological specialists; these mandates already exist in states containing almost 70 percent of the population. CBO estimates that about 20 percent of individuals in employer-sponsored plans would be newly affected by section 104(a) to a substantial extent. CBO relied on an estimate of the effect of this provision in California made by Price Waterhouse for the Kaiser Family Foundation which found that such plans could see a 1 percent increase in physician costs or a 0.35 percent increase in overall costs.² Thus, across all employer-sponsored plans, section 104(a) would raise employer-sponsored premiums by about 0.1 percent.

Section 104(b)—Specialty Care. Section 104(b) would require plans to pay for referrals to specialists when such care is justified by the complexity or seriousness of the condition and

2. Health Policy Economics Group, Price Waterhouse, LLP, "The Impact of Managed Care Legislation: An Analysis of Five Legislative Proposals from California" (November 1997).

the plan provides benefits for such treatment. If the referral were made to an out-of-network specialist, the patient could be charged no more than if the provider were participating in the network. The provision would also require a plan to establish a procedure for designating a specialist as the primary care provider when the plan is organized on a gatekeeper model and when the patient has a condition justifying coordination of care by a specialist. The plan would also have to establish a procedure for allowing standing referrals to a specialist when it was appropriate. Disputes arising out of this provision would be appealable under sections 132 and 133.

Although the provision does not explicitly specify that a plan would be required to refer a patient to a nonparticipating specialist, the provision would give appeal agencies the power to decide whether participating specialists had adequate expertise to treat the condition. Thus, this provision would stimulate appeals of plan decisions regarding virtually all aspects of referral management. Consequently, it would reduce the power of health plans in contract negotiations with specialists, especially sub-specialists concentrating on specific diseases or conditions. Patients and referring physicians could argue in the appeals process that certain centers of excellence or sub-specialists were uniquely qualified to treat unusual conditions. As these providers came to recognize the potential loss of plans' power to steer patients to designated specialists, they could become less willing to make fee concessions as a condition of joining the plan's network. These effects would be felt most heavily by the plans that rely heavily on provider discounts to achieve savings.

Plans would also have to establish new policies and procedures for dealing with requests for redesignation of specialists as primary care physicians in certain cases and for standing referrals. The setup and maintenance of such procedures would involve minor additional administrative costs. However, to the extent that patients with chronic conditions were assigned to specialists for primary care, the plan's pricing power with its other primary care providers could be reduced. Like section 103, this subsection would interact with section 108, which requires an adequate provider network. Therefore, CBO includes its cost in the estimate of section 108.

Section 105—Continuity of Care. This section would add about 0.2 percent to the average premium. During a transitional period, it would require employee health plans to pay for care delivered by a nonparticipating provider when the plan terminates its contract with a provider while a patient is receiving a course of care. The transition period would be 90 days, with a longer period allowed for pregnant or terminally ill patients. The termination could result either from dropping a physician from a plan's network or from deleting an insurance product from an employer's offerings of health plans. The right to transitional care would require health plans to adopt new systems and procedures for contracting with

providers and for handling transitions from one insurance plan to another. These systems would involve a one-time development cost as well as additional ongoing costs.

In the case of terminating a contract with an individual provider, the major cost to a plan would be the cost of notifying enrollees. Health plans generally gain or lose fewer than 10 percent of contracting physicians a year. Notification would involve identifying recent encounters by enrollees with terminated physicians and informing the enrollee of rights to transitional care, if the provider remained willing to accept the terms of the old contract.

In the case of terminating an insurance product, costs would increase not only because enrollees would have to be notified but also because systems and procedures would be required to administer the transition between plans. This system would require insurers to contract with willing out-of-plan providers for a limited period of time and incur costs associated with contract negotiations. The new health plan would be responsible for educating the out-of-plan provider about the plan's policies regarding quality assurance and utilization review. Although these arrangements could increase costs of health insurers and employers, they would also impose a burden on providers. Therefore, the aggregate cost of the claims exceptions process would be largely attenuated by its infrequent use.

Section 106—Coverage of Clinical Trials. This section would require health plans to pay for routine patient care associated with certain clinical trials sponsored by the National Institutes of Health (NIH), Department of Veterans Affairs (VA), Department of Defense (DoD), or NIH-sponsored cooperative groups. Only trials for life-threatening or serious illnesses for which no standard treatment is effective would qualify. The federal government's or cooperative group's contribution could be limited to in-kind contributions. The health plan would be required to pay for care at a rate no higher than it pays to participating providers, and it could require a patient to be treated by a participating provider, if such a provider was collaborating in the trial.

A high but declining portion of trial-related patient care costs is currently paid by private health plans.³ CBO estimates that health plans currently pay at least 90 percent of these costs. NIH personnel indicated that their supported clinical trials generally cover only the research costs (for example, data collection and statistical analysis) and sometimes the experimental therapy. Medical procedures or services are paid out of the research budget

3. Robert E. Mechanic and Allen Dobson, "The Impact of Managed Care on Clinical Research: A Preliminary Investigation," *Health Affairs*, Fall 1996, vol. 15, no. 3, pp. 72-89.

infrequently (for example, when they are performed exclusively to further a research objective and have no diagnostic or therapeutic value to the patient). Private sponsors or in-kind contributions by providers may play some role, but these sources of funding are likely to be small in the aggregate.

NIH-sponsored cooperative groups typically mount studies funded by private entities as well as NIH. For example, cooperative groups sponsored by the National Cancer Institute (NCI) receive funding from NCI to support a research infrastructure and a peer review process as well as for specific NCI-sponsored trials. However, they also conduct studies on behalf of private sponsors. As with NIH-sponsored studies, the private sponsor pays for research costs and often the experimental therapy but typically relies on insurers and health plans to pay for other care provided to participants in the trial.

CBO obtained estimates from NIH, VA, and DoD of the number of individuals who entered their sponsored treatment trials each year. Most of these entrants are under age 65, and most have private insurance. The estimate assumes that virtually all such trials would meet the test of being for serious or life-threatening illness for which no existing therapy is fully effective. The estimate also assumes that the bill would not require health plans to pay for treatments that would not be covered by the plan if they were not experimental.

Because the provision would reduce the cost of clinical trials to governmental and private sponsors, it would be likely to increase the number of patients enrolled in approved trials. At least three responses would occur. First, researchers would expand the size of trials to answer more research questions and to do so with greater precision. Second, more trials would be funded. Third, researchers would seek to test more expensive treatments.

CBO assumed that today each patient in an NIH-sponsored trial has costs of care that are 10 percent higher than the costs of similar patients who do not enter trials. This estimate is based on published and unpublished results of several small studies that compare costs of cancer patients in clinical trials with similar patients who are not in trials. Those studies have found smaller incremental costs, but they did not include the relatively infrequent trials involving highly expensive therapies (such as autologous bone marrow transplantation for breast cancer). The cost differential could be expected to grow in the future as new trials involve more expensive therapies.

CBO further assumed that the provision would triple the number of individuals enrolled in clinical trials gradually over the next 5 years. Although this figure may be an underestimate of the long-term effect, constraints on the availability of trained clinical research personnel would limit the rate of increase in the near term.

The provision would limit the payment that plans would have to make to nonparticipating providers, thereby providing large managed care organizations with some bargaining power over the design and cost of trials. Specifically, plans would be required to pay those providers the rates that they would normally pay to participating providers for “comparable services.” But disputes between nonparticipating providers and health plans could arise over the definition of comparable services. Those disputes could lead to suits under ERISA to enjoin violations of this provision. Depending on how the federal courts interpreted the provision, health plans might have little power to negotiate with protocol sponsors over rates of payment.

CBO estimates that this provision would ultimately increase the average premium across all kinds of employer-sponsored health plans by 0.5 percent.

Section 107—Access to Needed Drugs. Section 107(a) would require plans using restrictive drug formularies to have written policies and a process for making exceptions. CBO surveyed the evidence on current pharmaceutical benefits and concluded that virtually all drug formularies already have such processes in place.

Section 107(b) would prohibit a health plan from refusing to cover a drug or device that is approved by the Food and Drug Administration (FDA), when it is prescribed for the approved use, on the grounds that the treatment is experimental. This prohibition could create new administrative costs for health plans that currently rely on investigational technology clauses in their benefit contracts to deny payment for new treatments. These clauses allow plans to avoid conducting case-by-case reviews of medical necessity for some new technologies. CBO assumes that plans would gradually adjust to the new requirement by excluding some specific technologies from covered benefits and by using determinations of medical necessity to limit coverage for others. The additional administrative costs associated with these changes would be small, because few new technologies are excluded as investigational.

CBO estimates that this section would raise health plan costs by less than 0.05 percent.

Section 108—Adequacy of Provider Network. This section would require plans to establish networks that provide adequate and appropriate levels of availability of needed services. It provides little specific language defining what kinds of networks would be considered adequate or appropriate. CBO assumes that the requirements for consumer choice (section 103) and access to specialists (section 104(b)) would necessitate several participating providers within specialties and subspecialties in order to assure geographic proximity and timely access. Thus, this provision would put pressure on some plans to

augment their networks of providers. In conjunction with sections 103 and 104, this section would reduce the pricing power of plans when they negotiated contracts with providers. Depending on how it was interpreted by regulation, the requirement for an adequate network could require plans to become price-takers in areas with few physicians in certain key specialties and in small metropolitan areas or rural areas with few physicians in general. CBO estimates that the net effect of these potential impacts on health plan premiums is 0.2 percent for all employer-sponsored plans.

Section 109—Nondiscrimination in Delivery of Services. This section would prohibit plans from discriminating against health plan members in the delivery of health care services on the basis of race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment. Plans would not be prohibited from limiting health insurance coverage on the basis of pre-existing conditions or from charging higher premiums for such coverage. The boundary between a disability and a pre-existing condition is often unclear, however, and plaintiffs could sue under ERISA for injunctive relief on the grounds that determinations by health plans violated this section. CBO estimates that this provision would increase premiums by 0.1 percent.

CBO's estimate assumes that this provision would not prohibit health plans from excluding certain classes of health care services, such as prescription drugs or mental health services, from its contract benefits.

Quality Assurance

Subtitle B lays out a program for assessing and monitoring the care delivered and outcomes of care for plan members. It would require plans to set up an internal quality assurance program to oversee the collection of data on services and outcomes and to correct problems of quality; develop a set of standards and procedures for selecting participating providers, including verification of the provider's background; and, for plans with prescription drug benefits, have a quality improvement program that encourages appropriate use of prescription drugs and reduces the incidence of adverse drug interactions. It would also specify requirements for utilization review (UR), including standards of timeliness and involvement of clinical peers (that is, physicians) in the UR process.

Section 111—Internal Quality Assurance Program. This section would require each health plan or health insurer to maintain a separate office responsible for carrying out the provisions of the subtitle. The program would have a unit director and a written plan for quality assurance, with criteria for plan performance and patient outcomes. It also would

have a system to receive reports of quality concerns from providers and enrollees. And, it would have the capability of producing standardized clinical data. Federally qualified health maintenance organizations (HMOs) and plans accredited by a recognized accrediting organization would be deemed to comply with this requirement.

The estimate assumes that all health plans except those that are federally qualified HMOs or currently accredited by the National Committee on Quality Assurance would have to develop a new quality assurance unit (or upgrade an existing one), with a physician director, data analysts, nurse abstracters, and clerical support personnel. CBO estimates that establishing or upgrading these units would increase costs by 0.2 percent across all employer-sponsored plans.

Section 112—Collection of Standardized Data. The bill would require the collection and analysis of standardized data on the utilization of health care services, the demographics of enrollees, disease-specific mortality and (if feasible) morbidity, satisfaction with the plan, health outcomes, and indicators of quality. The exact requirements for data collection and analysis would be specified by the Secretary of Health and Human Services (HHS), subject to the recommendations of the Health Care Quality Advisory Board. The costs of collecting and analyzing data would depend on the data items selected and required by the Secretary. Because information systems vary widely, the costs of these reporting systems would fall unevenly on different types of plans. Some measures would be harder for tightly managed HMOs to produce, while others would be harder for broad network plans to produce.

Based on trends in data collection and quality measurement under the Medicare program, CBO assumed that the data items required by the Secretary would include all of the Health Plan Employer Data and Information Set (HEDIS) measures currently required under Medicare contracts, plus additional measures required for HEDIS accreditation in 1999, as well as new measures specifically required in the bill, such as disease-specific mortality. The Quality Improvement System for Managed Care proposed by the Health Care Financing Administration (HCFA) for all Medicare+Choice Plans would require them to produce HEDIS measures as well as other quality measures. So far, HCFA has made no separate arrangements for PPOs or other broad network plans, and the estimate assumes that the Secretary would make no special arrangements under this bill for such plans.

Some HEDIS measures could be compiled from administrative data (for example, electronic claims forms), especially if claims forms are altered to capture specific items required under HEDIS. However, most of the HEDIS measures required by Medicare involve reviewing the medical records (or charts) of a sample of beneficiaries—about 400 for each measure. Moreover, the HEDIS manual requires plans to perform chart reviews to verify some

measures when administrative data are inadequate. The estimate assumes that data requirements would be expanded gradually to include severity of disease or other risk-adjustment measures that could be measured reliably only through chart reviews.

Medicare's current rules for risk plans require two direct surveys of patients: a survey of consumer access and satisfaction and a survey of general health status. HCFA requires each Medicare plan to survey 1,000 enrollees. The estimate assumes that these surveys would also be required of private insurers, only in larger numbers because of the need to cover all age groups. The need for a survey of health status would be important for adjusting outcomes for differences in risk profiles among plans, so CBO assumes that sooner or later it would be part of the information package.

The estimate takes into account the likelihood that the minimal dataset would change from year to year, requiring continual software development. It also assumes that each health plan would be required to review the medical records of 2,000 patients each year. Some of these records would be in physicians' offices. The cost of this exercise would be higher for health plans with larger and more diffuse networks. CBO estimates that the provision would increase premiums by 0.2 percent on average.

Section 113—Process for Selection of Providers. This section would require plans that selectively contract with health care professionals to develop and maintain a written process governing their selection. The plan would have to verify the provider's professional license and determine whether the license had ever been suspended or revoked. The section would prohibit plans from excluding professionals on the basis of their location in areas with high-risk patients. Plans could not exclude certain kinds of professionals from participating solely on the basis of the class of certification or licensure, as long as the services the individual would deliver were within the scope of his or her license.

This provision would entail administrative costs to verify and update the status of licensure for both potential and currently participating professionals. Most plans already verify the credentials of participating providers, at least initially. In addition, these costs would largely overlap those of section 143 (regarding the participation of health care professionals). Consequently, CBO has included them in the estimate of section 143.

Section 114—Drug Utilization Program. Although the bill would require health insurers to operate a drug utilization review program, pharmacies and pharmaceutical benefits managers are currently providing these services. Thus, the incremental costs associated with drug utilization review would be small.

Section 115—Standards for Utilization Review Activities. This section sets out requirements for the conduct of utilization review activities. It would require plans to specify clinical review criteria developed with input from appropriate physicians and based on outcomes of care to the extent feasible. The requirements of the section are largely consistent with current practice in health plans that rely on utilization review. Therefore, CBO estimates this provision would increase health plan costs by less than 0.05 percent.

Section 116—Health Care Quality Advisory Board. This section would establish an appointed health care quality advisory board to identify, update, and distribute quality measures for health plans; advise the Secretary of HHS on the minimum data set; and advise the Secretary on standardized formats for this information. CBO estimates that the operations of the Health Care Quality Board would cost \$15 million over the 2000-2004 period, assuming appropriation of the necessary amounts.

Patient Information

Subtitle C would require health plans to provide information about policies governing their operations, as well as the quality-assurance data called for in subtitle B. It also requires health plans to protect the confidentiality of individually identifiable information. Finally, it calls for federal grants to states or nonprofit entities for new health insurance ombudsmen, whose job would be to assist consumers in their interactions with group health plans.

Section 121—Patient Information. The section contains a long list of information that plans would be required to provide to enrollees annually or to make available upon request. Much of the required information is typically provided now as part of a plan's handbook or could easily be incorporated into that document. Although a plan's documents would have to be amended to meet the requirements of this provision, such documents are continually updated in any event. The provision of this information as part of the plan document would not appreciably raise health care costs. Although the requirement that the plan provide information on all participating providers (for example, name, address, telephone number, availability, and credentials) might represent a new operation for many plans, the costs of this requirement should also be modest.⁴

Section 122—Protection of Patient Confidentiality. The provision requiring plans to safeguard enrollee information may impose a small additional cost on those employee health

4. U.S. General Accounting Office, *Consumer Health Care Information: Many Quality Commission Disclosure Recommendations are Not Current Practice*, April 1998 (GAO/HEHS-98-137).

plans that do not have formal policies on data confidentiality, but discussions with health insurance and managed care plan executives indicate that the requirements of this provision are general practice in the insurance business today. Moreover, the Health Insurance Portability and Accountability Act of 1996 requires the Secretary of HHS to promulgate regulations by February 2000, protecting the confidentiality of certain patient information (if the Congress fails to enact legislation by August 1999). Thus, this provision would not have a significant effect on premiums.

Section 123—Health Insurance Ombudsmen. This section would authorize the appropriation of such amounts as are necessary to provide grants to states to establish a health insurance ombudsman program. The ombudsman would be directed to assist consumers in choosing health insurance coverage and to help dissatisfied enrollees with appeals and grievances. If a state did not provide an ombudsman, the Secretary of HHS would provide one. CBO estimates that outlays for these grants would total \$55 million during the 2000-2004 period.

Grievance and Appeals Procedures

Subtitle D would require all group health plans and health insurance issuers to establish a system for handling enrollees' grievances, which would include a two-tier process for reviewing appeals of plans' decisions. The first stage would involve appeals to professionals within the plan. Enrollees who were not satisfied with that internal decision could then appeal certain grievances to an external appeals board.

CBO estimates that these provisions, which are highly interrelated, would jointly raise premiums by 0.3 percent. Because plans could require enrollees to exhaust all internal appeals before taking a grievance to the external review board, the number and type of claims that the external review board would consider would depend on the stringency of the internal appeals process. Conversely, having an external appeals process with binding authority over plans would affect both the number of internal appeals and the likelihood that the plan would decide in favor of the beneficiary.

Section 131—Establishment of Grievance Process. The bill would require group health plans and health insurance issuers to establish a system to provide for the presentation and resolution of grievances brought by enrollees or their representatives, including their health care providers, regarding any aspect of the plan's services. Plans would have to provide written notification to enrollees of whom to contact in the event of a grievance or appeal, establish systems to record and document all grievances and appeals and their status, develop

a process for timely processing and resolution of grievances and for follow-up actions, and ensure that the continuous quality improvement program would be informed of any grievances relating to the quality of care.

Section 132—Internal Appeals of Adverse Determinations. This section would establish an enrollee's right to appeal a wide range of decisions by their health plan, including denial, reduction, or failure to provide or pay for a benefit; failure to provide emergency coverage, choice of providers, qualified providers, access to specialty care, continuation of care if an enrollee's provider was terminated, access to necessary prescription drugs, or coverage of clinical trials; adverse utilization review decisions; and arbitrary interference with the physician's decision on the manner or setting of care, when the care was medically necessary or appropriate.

The bill would require individuals conducting internal reviews to include clinical peers who had not previously been involved in the decision under appeal. Clinical peers would be physicians or other health professionals with qualifications in the specialty that typically managed the condition or treatment involved in the appeal, but only a physician would be considered the clinical peer of another physician.

Group health plans and health insurance issuers would face limits on the time for resolving an appeal, which would vary according to the urgency of the situation. They would have to resolve expedited appeals within 72 hours of receiving them and all other appeals within 30 working days.

CBO's estimate assumes that although most health plans have functioning internal review systems, they would experience an increase in the rate of internal appeals per enrollee, as a result of greater consumer knowledge of the appeals process and the availability of external review. A recent study by the General Accounting Office suggests that data on internal appeals rates are highly unreliable and vary widely among HMOs.⁵ The range of self-reported appeal rates was 0.07 to 69.4 per 1,000 enrollees, with a median of 3.5. Those rates, however, included appeals for the denial of emergency services, which might occur less frequently under the bill because of the "prudent layperson" provisions. CBO's estimate, therefore, assumes a current average appeal rate, excluding appeals relating to emergency services, of 2.5 per thousand enrollees.

Health plans and health insurance issuers with internal appeals processes in place would still incur cost increases under the bill because of higher rates of appeal and higher costs per

5. U.S. General Accounting Office, *HMO Complaints and Appeals: Most Key Procedures in Place, but Others Valued by Consumers Largely Absent*, GAO/HEHS-98-119 (May 1998).

appeal. But appeal rates and costs will rise somewhat even without the legislation. Increases will occur under current law if proposed regulations affecting internal claims procedures for ERISA health plans proposed by Department of Labor (DoL) are adopted.⁶ The regulations will require ERISA plans to provide enrollees whose claims are denied with information on their appeal rights and will require plans to meet tighter timeframes both for the initial review of claims and for subsequent appeals.

Nonetheless, CBO assumes that the enactment of this bill would raise internal appeals rates among ERISA plans, as well as among the non-ERISA plans that would be required to comply. Because of the provisions for external review of denied appeals and the penalties for health plans that did not comply with the legislation, the bill would provide much stronger incentives for internal appeals than the DoL regulations alone.

Costs per appeal would also rise for ERISA and non-ERISA plans as a result of the legislation. Factors contributing to higher costs include:

- o The requirement for review by a clinical peer, which will result in higher professional costs for internal appeals and
- o Higher rates of appeals being overturned in favor of enrollees, reflecting plans' desire to avoid external review.

Plans would attempt to reduce the cost of appeals by applying less stringent utilization review standards to appealable decisions, provided that such responses would lower their overall expected costs.

Cost increases would be larger for the small minority of health plans and issuers that do not currently have systems for internal review of grievances in place. They would experience a significant increase in administrative costs as well as the costs associated with overturned decisions resulting from appeals.

Section 133—External Appeals of Adverse Determinations. This section would require all health plans and health insurance issuers to establish a process whereby enrollees could appeal plans' decisions to an external review organization, which would provide a *de novo* determination of the merits of the claim. Decisions in any of the internal appeal categories would be eligible for further appeal if the costs at issue exceeded a significant threshold, or if the patient's life or health would be jeopardized. The plan or issuer could require the

6. Federal Register, Wednesday, September 6, 1998, Department of Labor, Employee Retirement Income Security Act of 1994; Rules and Regulations for Administration and Enforcement; Claims Procedure; Proposed Rule.

appellant to exhaust the internal appeals process first before taking a claim to external review. But enrollees could take a claim directly to external review if the plan failed to comply with the deadlines for internal appeals in the law. The decision of the external review organization would be binding on the plan or issuer but would not affect the enrollee's right to seek judicial remedies in the courts. Decisions would have to be made within 60 days of filing notice of appeal or 72 hours in the case of expedited appeals.

Plans and issuers would have to contract with qualified external appeals entities. States could designate such entities for health insurance issuers and the appropriate Secretary for group health plans. External review organizations would have to meet certification and recertification requirements imposed by the states or the Secretary of Labor. But if a state did not establish an adequate certification and recertification process, the Secretary of Health and Human Services would fulfil that function.

Although about half of the states already require external appeals processes, few claims are appealed. Various factors appear to have contributed to that outcome, including:

- o Lack of awareness by enrollees of their external appeal rights because programs are new or not widely promoted;
- o Coverage of certain functions only, such as experimental procedures;
- o Uncertainty about whether the state's requirements are preempted by ERISA; and
- o Sentinel effects of having an external review program, which causes plans to modify their internal review procedures.

Florida is one of the few states that appears to have a program that is functioning at much more than a minimal level. And even Florida's rate of external appeals, about 1 per 10,000 enrollees, is only about one-tenth of the external appeals rate in the Medicare program.⁷ The Medicare rate, however, is higher than would be expected under the bill because every form of denial in Medicare is subject to appeal, and all appeals that plans deny are automatically referred to external review.

For the purposes of this estimate, CBO assumed that the legislation would significantly increase external appeals rates, even in those states that nominally have external review

7. Allen Dobson and others, "Consumer Bill of Rights and Responsibilities Costs and Benefits: Information Disclosure and External Appeals" (report submitted by The Lewin Group, Inc., to the Presidential Commission on Consumer Protection and Quality in the Health Care Industry, November 1997).

requirements. Moreover, those rates would rise over time as enrollees became more aware of their rights to such reviews. Nonetheless, external review rates would remain relatively low when compared to internal appeals rates (which plans would be more likely to resolve in favor of the enrollee if an external review option was available). Specifically, CBO estimated that external appeals rates would rise to about 4 per 10,000 enrollees after 5 years.

Protecting the Doctor-Patient Relationship

Subtitle E contains four provisions governing plans' contracts with providers.

Section 141—Prohibition of Interference. This section, an anti-gag-rule provision, would void any provision of a contract that limited a provider's freedom to discuss or communicate with a patient about aspects of his or her care. Several studies have shown that few plans impose such restrictions today. For those that do, their costs associated with this provision would be minimal.

Section 142—Prohibition of Improper Incentive Arrangements. This section would prohibit provisions in contracts between health plans and providers that transferred liability for decisions of the plan to the provider or rewarded the provider for decisions regarding specific patients. Although health plans might seek to reduce their own potential liability for medical negligence under the bill by transferring that liability to providers, their costs would not be affected because they would have to pay more to providers to cover the transferred costs of liability. The prohibition of physician incentive plans that financially reward or penalize physicians for decisions involving specific patients would follow guidelines promulgated for Medicare HMOs. Those guidelines require physicians who take substantial financial risks to have stop-loss insurance covering the risk of high-cost patients. The section would have a small impact on premiums overall.

Section 143—Participation of Health Care Professionals and Section 144—Protection for Patient Advocacy. These sections would establish protections for providers that generally do not exist in health plans today. Section 143 would specify due process standards for selective contracting between plans and health care professionals. Section 144 would protect providers (and enrollees) from retaliation for participating in the appeals and grievance process or for disclosing information on the quality of care to a plan or regulatory agency. Under title III, physicians and other professionals could appeal adverse contractual decisions by ERISA health plans to the Secretary of Labor on the basis of this provision. Title III also would prohibit retaliation against professionals by institutional health care providers.

Although these protections would be largely procedural (for example, requiring written rules on participation but not dictating the content of those rules), they would require plans to establish regulatory compliance operations for their contractual interactions with providers. Plans would not only need to establish compliance with sections 113, 143, and 144, but they would also have to defend against the threat of appeal through careful documentation of all contract actions. Thus, although these sections fall well short of constituting any-willing-provider provisions, they would entail some administrative costs.

The provisions would fall most heavily on managed care plans with broader networks, such as preferred provider organizations and independent practice associations, which do not typically have exclusive arrangements with physicians and hospitals. CBO estimates that the incremental costs of these provisions would be 0.2 percent of premiums.

Promoting Good Medical Practice

Subtitle F contains a specific benefit mandate and a more general provision prohibiting arbitrary interference with medical practices. The benefit mandate relates to treatment of breast cancer.

Section 151—Promoting Good Medical Practice. This section would prohibit plans from arbitrarily interfering with or arbitrarily altering the manner or setting of care when that care is medically necessary or appropriate. Manner or setting would be defined as the location of treatment and the duration of service but would exclude decisions on the plan's coverage of particular services or treatments. The section defines medically necessary or appropriate care as care that is "consistent with generally accepted principles of professional medical practice." Grievances regarding the plan's conformance with this section could be appealed under subtitle D. Members of ERISA plans could also sue in federal court to seek remedies under this provision.

This section could affect plans in two ways. First, it would increase the expected costs of utilization review and reduce the potential savings from such activities. Second, it could restrict plans' ability to use more indirect methods of influencing utilization, such as financial incentives for education of providers.

The section would establish the right to appeal plans' utilization review decisions about the appropriateness of inpatient, outpatient or home care for procedures or treatments, monitoring of high risk patients, and administration of medications, as well as all decisions

about lengths of inpatient stays. Any decisions regarding those categories of care would be subject to the provision's definition of medical necessity.

Because the provision would put the burden on the plan to prove that a given practice was not "consistent with generally accepted principles of professional medical practice" any appeal would require the plan to develop substantial evidence that the physician's decision was unreasonable. This provision would increase the volume of internal and external appeals above and beyond the volume expected from other provisions. Not only would the provision provide additional incentives to appeal decisions by plans, but it would probably also lead to a higher rate of reversal on appeal. Although the external appeals bodies might eventually settle on uniform and easily interpreted standards of medical necessity, the variability of medical practice styles across the country would ensure continuing challenges to decisions by plans over the 10-year estimating period.

One way for plans to avoid appeals under this provision would be to reduce the frequency with which they challenged physicians' decisions. CBO took account of the likelihood that plans would adopt defensive utilization review practices when the costs of such changes to the plan were lower than the expected costs of the internal and external review actions required to defend the UR policies. The burden of this provision would fall more heavily on those health plans with broader networks which rely on utilization review to influence patterns of care. Traditional indemnity plans with utilization review components, preferred provider organizations, and non-capitated independent practice association-model HMOs would face more appeals than would group- or staff-model health maintenance organizations. CBO estimates that the higher volume of internal and external appeals and the higher probability of decisions unfavorable to plans would raise premiums by 0.8 percent overall.

Section 152—Standards for Breast Cancer Treatment. Section 152 would prohibit health plans from limiting hospital lengths of stay for mastectomies to less than 48 hours and for lymph node dissections for breast cancer to less than 24 hours. The provider would not have to obtain prior authorization for any length of stay for those conditions. CBO estimated that these two provisions would add less than 0.05 percent to health plan premiums.

Changes to the Employee Retirement Income Security Act

Title III of the bill would apply the patient protection standards of title I to group health plans and group health insurance coverage under ERISA. The estimated costs of these standards were discussed above. In addition, title III would impose additional regulatory costs on the

Department of Labor and would alter the legal liability of health insurance plans under ERISA.

Enforcement by the Department of Labor. Section 301 would permit any health care professional who has been discriminated against or retaliated against to file a complaint with the Secretary of Labor. The Secretary would be required to investigate these complaints to determine if a violation had occurred. If a violation occurred, the Secretary would issue an order to ensure that the health professional did not suffer any loss of position, pay or benefits from the plan. Costs associated with this enforcement include the expenses associated with tracking and investigating complaints by providers. CBO estimates that these costs would total \$190 million over the 2000-2004 period, assuming appropriation of the necessary amounts.

Legal Liability for ERISA Plans. As a result of ERISA, enrollees in employer-sponsored health plans are generally unable to seek legal remedies under state law for damages resulting from the actions or decisions of their health plans. They may seek redress only in federal court under the provisions of ERISA, which limits any damages to the cost of the plan benefits under dispute and, in some cases, attorneys' fees and court costs. In recent years, ERISA case law has evolved, with some federal courts ruling that enrollees can sue their plans in state courts for vicarious liability for the medical negligence of the plan's providers. But disputes over benefits and administration have largely been preempted by ERISA.

The bill would amend ERISA to allow enrollees in employer-sponsored plans (or their estates), under certain circumstances, to sue their health plans under state law for damages resulting from personal injury or wrongful death. Specifically, enrollees could sue a person if personal injury or wrongful death resulted from that person's provision of insurance, administrative, or medical services to or for a group health plan, or arose out of their arrangement for the provision of insurance, administrative, or medical services by others. The bill would protect employers and other plan sponsors from suits as long as the action that led to the suit did not reflect the exercise of discretionary authority by the employer or sponsor. The cost of this provision depends on assumptions for which the supporting data are extremely limited or nonexistent. CBO therefore consulted with many experts nationwide on the likely outcomes of this provision and received a broad range of opinions.

Some experts believe that ending the ERISA preemption for health plan liability would increase costs only slightly. They maintain that the bill would do little more than speed up trends that are already underway in the courts of holding ERISA plans accountable for the medical negligence of their providers and treating adverse outcomes resulting from decisions on medical necessity by health plans as medical negligence. Health plans could limit their

liability for decisions on medical necessity by including more explicit coverage statements in their contracts and by using binding arbitration or other alternative dispute resolution techniques. Moreover, the external review requirements in the bill would limit the number of cases that would be litigated, and the caps on tort liability that exist in more than half of the states would limit the size of awards. These experts also argue that the experience of state and local government health plans and among plans in the individual insurance market, all of which are exempt from ERISA and potentially subject to litigation, suggests that litigation over issues relating to denial of coverage is likely to be small.

Others believe that ending the ERISA preemption would fundamentally change the environment in which private employer-sponsored plans operate and increase their costs considerably, not only as a result of litigation but also because of the defensive utilization review strategies that plans would adopt. They predict that health plans would be sued along with providers for medical malpractice much more frequently when patients were injured, because of the plans' "deep pockets" and because lawyers would not have to deal with potential issues of ERISA preemption and would be attracted by the large damages that juries might award. A big increase in suits over decisions on medical necessity and denial of coverage would probably occur, they contend, with providers as well as beneficiaries seeking damages. Health plans' attempts to limit coverage contractually could be thwarted by arguments that such contractual restrictions were another form of practicing medicine and, hence, subject to suit. Whether state tort liability caps would apply to health plans is uncertain and would probably vary among the states. In addition, the language in the bill protecting employers and sponsors who were not exercising discretionary authority would not protect the fiduciaries of ERISA plans who, by definition under the law, exercise such authority. Proponents of these views also argue that the experience of non-ERISA plans does not throw much light on what would probably happen in the ERISA market because of differences in the covered populations (including the degree of unionization), appeals processes, plan generosity, and choice of plan, as well as states' ability to limit their legal liability. They envision the emergence of an aggressive plaintiffs' bar that would declare open season on health plans.

The bill includes several provisions designed to address some of those concerns:

- o Only plan participants and beneficiaries (or their estates) would have standing to file suit;
- o The term "personal injury" is defined to mean physical injury, including an injury arising out of the treatment, or failure to treat, a mental illness or disease;

- o The limitation on suits against employers and plan sponsors also includes their employees when acting within the scope of their employment; and
- o A construction clause establishes that nothing in section 302 should be construed as permitting a cause of action under state law for the failure to provide an item or service that the group health plan did not cover.

Regardless of the extent to which they are subject to suit under current law, all health plans are already, directly or indirectly, incurring significant liability costs. Most of those costs relate to medical negligence, as litigation over coverage questions has been relatively rare (in part, because of the ERISA preemption). Tightly managed plans are at risk for being held vicariously liable for the medical negligence of their providers. To offset that risk, they may purchase liability insurance, establish mandatory arbitration procedures, or increase their oversight and monitoring of providers. Loosely managed and indemnity plans pay liability costs indirectly through the rates that they pay to providers, which include those providers' liability insurance costs. Those types of plans also pay for additional services that result from physicians' defensive practices. CBO estimates that health plans' liability costs average about 2 percent of their premiums (not counting defensive medicine by providers).

Several factors could cause plans' expected liability costs to rise.

- o More medical negligence suits would be filed against ERISA plans, and the amount of damages awarded would rise, as plaintiffs would have another party to sue in addition to the provider. Although some of those suits are occurring now, dealing with the issue of ERISA preemption is a disincentive for many medical malpractice lawyers and reduces the number of suits that are filed.
- o Expected liability costs associated with decisions on medical necessity and coverage would increase significantly. At present, there are few coverage suits against ERISA plans as a result of the preemption, and the associated liability costs are low. Ending the ERISA preemption would mean not only that more plans would be successfully sued but, more importantly from a cost perspective, every judicial decision awarding damages to a plaintiff for a plan's coverage decision would increase the risk of suit for all other plans with similar coverage policies. Several of the experts whom CBO consulted mentioned the *Fox v. Health Net* suit as an example of that phenomenon.⁸ The jury in *Fox* awarded the plaintiff, a breast cancer patient, \$89 million for denial of coverage of autologous bone marrow transplantation (ABMT). Although the case

8. *Fox v. Health Net*, Riverside Superior Court, March 26, 1994.

was subsequently settled for a much lower amount, expected liability costs rose for all health plans with similar coverage standards for ABMT. Consequently, many plans apparently took action to reduce their risks from such suits, changing their utilization review criteria for ABMT so that the treatment became much more widely utilized. (Plans could have handled the increased risk in a variety of ways, of which loosening their utilization review criteria was just one. Alternatively, they might have increased their liability insurance or changed the coverage standards written into their contracts with enrollees.) Two recent suits (*Johnson v. Humana* and *Goodrich v. Aetna U.S. Healthcare of California, Inc.*) provide further indications of the potential for juries in state courts to award large punitive damages to enrollees who argue that they have been injured by their plans. Such awards serve as sentinel events that can have far-reaching effects on the behavior of all health plans, not just those that are sued.

- o The bill is likely to result in a variety of unforeseen lawsuits against health plans—including suits instigated by providers and suits against plan fiduciaries. Section 302 would raise new issues regarding the extent of the ERISA preemption that could take the courts a long time to address.
- o In addition to the increase in direct liability costs that plans would face, plans would also have to consider the indirect costs associated with the adverse publicity that litigation engenders. Adverse publicity could result in loss of market share, adding to plans' expected liability costs.

Taking all of those factors into account, CBO estimates that ending the ERISA preemption of legal liability for private employer-sponsored plans would increase liability costs by 70 to 90 percent, in the case of PPOs, POS plans, and HMOs, and by a lesser percentage in the case of indemnity plans. Those increases represent, on average, about 1.4 percent of the premiums of all employer-sponsored plans. Those estimates take into account all of the actions that plans take to lessen their liability costs, including the purchase of liability insurance and changes in utilization review criteria and coverage standards intended to reduce the probability of lawsuits.

Under CBO's assumptions, more than half of the increase would arise from potential suits associated with decisions on medical necessity and coverage (and the associated behavioral responses by plans), as well as lawsuits involving providers and plan fiduciaries. Most of the remainder would result from more medical negligence suits against plans, reflecting the financial resources of health plans and the effects of the new legal environment. The estimate also assumes that a further loosening of review criteria and standards of medical

necessity (with a corresponding increase in costs) would result from the desire of plans to avoid the adverse publicity of litigation.

Questions have been raised about the impact of the health plan liability provisions on small self-insured firms. Advocates for small businesses argue that liability insurance is not currently available for such firms, and they would be unlikely to remain self-insured without liability coverage if the ERISA preemption was lifted. Purchasing a fully-insured plan from an insurer or an HMO, which the firms might feel compelled to do, would increase their insurance costs because they would have to pay for benefits mandated by the state as well as state premium taxes. In addition, they could face a one-time cash flow problem because they would have to start making premium payments to an insurer while they were still paying off the tail of claims from their own plan.

Although temporary dislocations might occur when these provisions first came into effect, insurance markets would almost certainly respond to the demand for liability coverage for health plans. Third-party administrators that service small self-insured plans, and insurers that offer risk-sharing arrangements to such plans, would have a strong incentive to develop the means for self-insured plans to obtain liability coverage. In order for liability insurers to be willing to provide such coverage at a reasonable premium, however, the plans might have to accept more oversight and standardization of their coverage policies, which could increase their costs. In addition, obtaining liability coverage for punitive (as opposed to compensatory) damages might be a problem in the 15 or so states in which the courts have ruled that punitive damages are not insurable. But punitive damage awards are capped in at least some of those states, which would limit the risk for a firm without coverage for punitive damages.

The transition period until liability coverage was more generally available could be difficult for some self-insured firms, with some of them opting to purchase fully insured products rather than face an uncertain risk of liability. To the extent that response occurred, average premium costs would be higher than they otherwise would be, but the effects would diminish over time as markets for liability insurance developed. Offsetting any subsequent decline in premiums, however, would be rising costs resulting from the growth in liability suits as more consumers (and their lawyers) became aware of their rights to sue health plans.

Two other factors would have offsetting effects on the costs of ending the ERISA preemption for health plan liability. On the one hand, some experts believe that the courts will continue on their current path of limiting the extent of the ERISA preemption, not only for medical negligence but also for decisions on medical necessity and coverage. Insofar as that occurred, then the additional costs resulting from this legislation would be lower, although

there is considerable doubt about how long it would take to establish this expanded body of ERISA case law. On the other hand, ending the preemption could have long-term consequences for the development and adoption of costly new technologies. Research suggests that the spread of managed care may have slowed the rate of adoption of new medical technologies, helping to contain the rate of growth of health spending.⁹ Because the bill would allow enrollees to sue plans for their decisions on medical necessity and coverage, the dissemination of new technologies would speed up, encouraging further technological development and raising costs.

Other Federal Administrative Costs

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires the Secretary of HHS to enforce provisions of HIPAA that apply to group or individual health insurance if she determines they not being enforced by a state. The Secretary currently enforces provisions of HIPAA in four states.

The Secretary would also be required to enforce the provisions of this bill, as they apply to group and individual health insurance, if she determines they are not being enforced by a state. CBO assumes that enactment of those provisions would increase to five the number of states subject to Federal enforcement. Over ten years, however, the number of states subject to Federal enforcement would decline to one. The estimate assumes that the average cost per state of enforcing S.6 would be the same as the average cost of enforcing HIPAA. Assuming appropriation of the necessary amounts, federal discretionary spending would increase by \$5 million in 2000, and by \$55 million in 2000-2004.

PAY-AS-YOU-GO CONSIDERATIONS

Section 252 of the Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in the Table 3. For the purposes of enforcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted. As noted earlier, this bill could reduce some of the savings associated with the spillover effect of managed care. Due to uncertainty about the existence or magnitude of the change, CBO has not included an estimate of Medicare costs.

9. David M. Cutler and Louise Sheiner, *Managed Care and the Growth of Medical Expenditures*, (NBER Working Paper No. 6140, Cambridge, MA: National Bureau of Economic Research, August 1997).

TABLE 3. ESTIMATED PAY-AS-YOU-GO EFFECTS OF THE PATIENTS' BILL OF RIGHTS ACT

	By Fiscal Year, in Millions of Dollars									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Change in Revenues	-270	-680	-1,070	-1,320	-1,530	-1,660	-1,750	-1,850	-1,950	-2,060
Change in Outlays	5	10	20	25	35	40	45	45	50	55

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

The PHSA allows state, local, and tribal governments to elect not to have certain federal requirements apply to their own group health plans. The requirements for state, local, and tribal governments in this bill would also be optional under the provisions of the act. Consequently, the bill does not contain intergovernmental mandates as defined in UMRA. The bill would affect the budgets of state, local, or tribal governments only if they chose to comply with the requirements on group health plans. If they chose to apply the bill's requirements to their own health plans, the budgetary impact on state, local and tribal governments could be significant. Because the bill imposes a number of new requirements on insurance issuers, state and local governments also may face increased costs if they offer fully insured products as part of their employee benefits plans. The bill would provide grants to states to establish a health insurance ombudsman, but in the absence of state activity, the federal government would assume responsibility for the office.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains several private-sector mandates as defined in the Unfunded Mandates Reform Act. CBO estimates that the direct cost of those requirements to private sector entities would significantly exceed the threshold specified in UMRA (\$100 million in 1996, adjusted annually for inflation) in every year following enactment (see Table 4).

TABLE 4. ESTIMATED DIRECT COST OF THE PRIVATE-SECTOR MANDATES IN THE PATIENTS' BILL OF RIGHTS ACT

	By Fiscal Year, in Millions of Dollars				
	2000	2001	2002	2003	2004
Provisions in Title I ^a	2,900	6,200	8,700	10,700	12,900

SOURCE: Congressional Budget Office.

a. Includes the items listed in Table 2, with the exception of sections 116, 123, and 302.

Most of the provisions of title I would impose requirements on both group and employer-sponsored health plans and on health insurance issuers. The mandatory point-of-service requirement in section 102 would affect only group and employer-sponsored plans, however, and the continuity of care requirement in section 105 would have almost all of its effect on that market as well. The provisions establishing the Health Care Quality Advisory Board (section 116) and the Health Insurance Ombudsman (section 123) would not impose mandates on private sector entities. CBO estimates that the total direct costs of the mandates in title I would be about \$3 billion in 2000 and would reach about \$13 billion in 2004. The costs in 2004 would represent about 3.4 percent of total private-sector health insurance expenditures, although their distribution among health insurance plans would be uneven.

Section 302 would amend ERISA to allow enrollees in employer-sponsored plans to sue their health plans under state law for damages resulting from personal injury or wrongful death. That provision would not constitute a mandate on private health plans. Rather, it would convey a new right that members of ERISA plans could exercise at their discretion.

COMPARISON WITH PREVIOUS ESTIMATES

On April 23, 1999, CBO provided an estimate of S. 6, as introduced. This estimate reflects two modifications offered by the sponsors.

The first modification deletes subparagraph 132(c)(2)(C) of the introduced bill, which required appeals to be expedited at the request of a physician. This change reduces the estimated increase in premiums for employer-sponsored health insurance by about 0.3 percentage points.

The second modification adds a new section 502(n) of ERISA, which would limit the ability of participants in health plans to bring legal actions to enforce certain provisions of S. 6 under subsections 502(a)(1)(B), 502(a)(2), and 502(a)(3) of ERISA. Under the bill as modified, participants could not initiate class actions or sue to obtain plan-wide injunctive relief under these provisions of ERISA. Legal relief would be limited to the provision of or payment for benefits or services denied to the individual participant. The limitation would not apply to complaints of discrimination in the delivery of services under section 109 of S. 6. This change reduces the estimated increase in premiums for employer-sponsored health insurance by 1.0 percentage point.

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